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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,415

09/12/2003

Andrew Vaillant

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EXAMINER

HURT, SHARON L

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,415	Applicant(s) VAILLANT ET AL.	
	Examiner SHARON HURT	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, 18, 21, 23, 27, 28, 30-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 33-37 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 14, 17-18, 21, 23, 27-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendments to the claims filed February 19, 2008 have been acknowledged and entered. Claims 1, 14, 21, 23 and 31 are currently amended.

Status of the Claims

Claims 1-14, 17-18, 21, 23, 27-28, 30-37 and 40-42 are pending. Claims 15-16, 19-20, 22, 24-26, 29 and 38-39 have been cancelled. Claims 3-13, 33-37 and 40-42 have been withdrawn from consideration. Claims 1-2, 14, 17-18, 21, 23, 27-28 and 30-32 are under examination.

Election/Restrictions

Newly submitted claims 40-42 are directed to species that are independent or distinct from the invention originally claimed for the following reasons: The Election/Restriction, filed March 10, 2006, did not have an election of species because the original set of claims did not contain any specific sequences, i.e. all claims were generic. The amended set of claims, filed May 24, 2007, added new claims which included specific sequences. The species recited in these claims are distinct from those cited by the examiner in the previous Office actions. The possible number of sequences to be searched is 4^n where n is the length of the oligo in nucleotides. Each sequence has a unique structure and requires an independent search in the art which is a burden to the Examiner.

Since no generic claim has been found allowable, no additional species will be searched at this time. Accordingly, claims 40-42 are withdrawn from consideration as being directed to

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non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03. The Office apologizes for not clarifying this issue in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-2, 14-15, 17-18, 21, 23, 27-32, 38-39 and 41-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the invention is drawn to the treatment of a virus infection with one oligonucleotide **is withdrawn** pursuant Applicant's amendments to the claims.

The rejection of claims 1-2, 14-15, 17-18, 21, 23, 27-32, 38-39 and 41-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims are drawn to at least one pharmaceutical oligonucleotide at least 10 nucleotides in length **is withdrawn** pursuant Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 1-2, 14-15, 17-18, 21, 23, 27-32, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Peyman et al. in view of Milligan et al. **is withdrawn**. Applicant's arguments, filed February 19, 2008, have been fully considered and are persuasive in view of the amendments to the claims.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. The claim is drawn to a method wherein said oligonucleotide is a randomer oligonucleotide. This does not particularly point out and distinctly claim the invention because a single oligonucleotide can not be a randomer. See the definition in paragraph 61 of the specification:

In the present application, the term "randomer" is intended to mean a single stranded DNA having a wobble (N) at every position, such as NNNNNNNNNN. Each base is synthesized as a wobble such that this ON actually exists as a population of different randomly generated sequences of the same size.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 14, 17-18, 21, 23, 27-28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Krieg et al. (US Patent 6,207,646, March 27, 2001).

The claimed invention is drawn to a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection in a subject, preferably a human, comprising administering at least one pharmacologically acceptable oligonucleotide at least 10 nucleotides in length, wherein said oligonucleotide comprises at least one phosphorothioate linkage and wherein the anti-viral activity of said oligonucleotide occurs principally by a non-sequence mode of action, wherein the method comprises at least one antiviral randomer oligonucleotide, wherein said oligonucleotide is non complementary to any portion of the genomic sequence of RSV or parainfluenza virus, wherein said oligonucleotide is at least 40 nucleotides in length, wherein said oligonucleotide

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comprises at least one modification to the its chemical structure or at least one 2'-modification to the ribose moiety, wherein said oligonucleotide is double stranded, binds to one or more viral components, wherein at least a portion of the sequence of said oligonucleotide is derived from a viral genome, wherein the method comprises a mixture of at least two different antiviral oligonucleotides.

Krieg et al. (hereinafter Krieg) teaches a method for the treatment of infectious viruses, including parainfluenza viruses and respiratory syncytial virus (RSV) (col. 10, lines 24-54) by administering an immunostimulatory nucleic acid molecule (col. 6, lines 50-58). Krieg teaches the oligonucleotides with CpG motif can range in length from 5 to 42 bases (col. 14, lines 13-18) and preferably have phosphorothioate linkage because a phosphorothioate backbone has been found to preferentially activate B-cell activity (col. 13, lines 5-15). Krieg teaches oligonucleotides are able to enter cells in a sequence independent mode of action (col. 1, lines 35-40). Krieg teaches oligonucleotides have enhanced immunostimulatory activity on human cells (col. 6, lines 34-40). Krieg teaches the oligonucleotides often comprise a ribose sugar and have substituted organic bases or purine (col. 12, lines 12-19). Krieg teaches the immunostimulatory nucleic acid molecule can be double stranded or single stranded but double stranded molecules are more stable in vivo (col. 11, lines 16-20). Krieg teaches proteins can specifically bind multiple other nuclear factors (col. 5, lines 19-22). Krieg teaches the oligonucleotides can be mixed phosphorothioate and methylphosphonate oligonucleotides (col. 26, lines 60-62). Claim 14 is included in this rejection because a randomer would necessarily include the sequence taught by Krieg.

Response to Arguments

Applicant's arguments will be discussed as they pertain to the new grounds of rejection. Applicant argues that Peyman et al. only teaches that antisense oligonucleotides have antiviral activity and is only enabled for four antisense oligonucleotides against HIV-1 in cell culture. Applicant argues that nowhere is it taught or even suggested in Peyman et al. that oligonucleotides have antiviral activity against multiple viruses acting by a non-sequence complementary mode of action. Krieg et al teaches sequence independent mode of action using immunostimulatory oligonucleotides to treat several different viruses.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334.

The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

July 29, 2008

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648